Amendment to the Drawings

The attached sheet, attached hereto in Tab D, includes changes to FIG. 20A. This sheet, which includes FIGS. 17-19, 20A and 20B, replaces the original sheet including FIGS 17-19, 20A and 20B.

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 29-52 are pending in the subject application.

Claims 1-28 were previously canceled.

Claims 38-41 were withdrawn from consideration as the result of an Examiner's earlier restriction requirement and are canceled in the foregoing amendment. In view of the Examiner's restriction requirement, Applicants reserve the right to present the above-identified withdrawn claims in a divisional application.

Applicants affirm the election of claims 29-37 and 42-52.

Claims 29-37 and 42-52 stand rejected under 35 U.S.C. §102, 35 U.S.C. §103, and/or 35 U.S.C. §112, first paragraph. Claims 44-46 were objected to because of identified informalities.

Claim 29 was amended to include the limitations of claim 30 and claim 30 was canceled.

Claim 31 was amended so it now depends from claim 29.

Claim 37 was amended to avoid a possible concern with the preamble of the claim.

Claim 42 was amended to include the limitations of claim 43 and claim 43 was canceled.

Claims 44-46 were amended to address the Examiner's objections and claim 44 also was amended for consistency of language (*i.e.*, member changed to device).

Claims 51 and 52 were re-written in independent form.

The amendments to the claims are supported by the originally filed disclosure.

The specification including the TITLE and the ABSTRACT, were objected to and correction required. The drawing figures were objected to and correction required. The specification including the abstract was amended to address the Examiner's objections and/or rejections. Enclosed herewith is an amended drawing figure that address the drawing objections.

The amendments to the specification and drawing figures do not introduce new matter because they either are editorial in nature or are supported by the originally filed disclosure.

35 U.S.C. §112, FIRST PARAGRAPH REJECTIONS

Claims 51-52 stand rejected under 35 U.S.C. §112 because the subject application fails to provide a written description as indicated on pages 5-6 of the above-referenced Office Action. Specifically, the Examiner questioned the support for the limitation which indicated that the opening formed in each of the conjunctiva and the sclera would be of a size such that sutures are not needed to prevent fluid escaping from within the eye while the entry alignment device is disposed in the opening in the conjunctiva and the sclera during the surgical procedure. Applicants respectfully traverse.

As indicated throughout the subject application, the present invention is directed to methods and instruments that would not involve the use of sutures as with conventional or existing techniques in connection with any incisions or openings that are made in the sclera (wall of the eye) in connection with for example a vitroretinal surgical procedure. For example, and as discussed in more detail in connection with the prior art rejection under 35 U.S.C., §102, in conventional procedures (*e.g.*, see Banko, col. 6, lines 15-30) sutures are used to tighten the incision about the instrumentality being inserted through an incision during a procedure. In addition to fixing or positioning the instrumentality within the incision, the sutures also seal the incision so that fluid does not leak from the eye past the instrumentality.

The opening formed in the sclera and conjunctiva by the penetrating member allows the entry alignment device of the present invention to be received therein without the need for sutures. As is explained herein, as the conjunctiva remains positioned over the sclera, after the sclera is being penetrated by the penetrating member and the entry alignment device, it is not possible for one to access the sclera to provide sutures to cause the opening to seal about the entry alignment device. Thus, for the entry alignment device and methodology of the present invention sutures are not needed to prevent fluid escaping from within the eye while the entry alignment device is disposed in the opening in the conjunctiva and the sclera during the surgical procedure.

Applicants have referred the Examiner to the discussion in connection with the §102 discussion, so that duplicative arguments are not provided in the within Response.

In sum, as the method and devices of the present invention are directed so that sutures are not needed to seal the opening formed in the sclera (sealed during or after the procedure), the feature that the penetrating member is configured and arranged so as to be inserted through each of the conjunctiva and the sclera, and so as to form an opening in the sclera of a size such that sutures are not needed to prevent fluid escaping from within the eye while the entry alignment device is disposed in the opening in the conjunctiva and the sclera during the surgical procedure is described in the subject application as it is an attribute of the sutureless methodology of the present invention. Applicants had set forth this limitation as a means to distinguish art, like Banko, in which sutures are being used for sealing when the device is in the incision. In such a case, such an arrangement necessarily means that the conjunctiva is being dissected to give the surgeon access to the sclera so they can suture.

Accordingly, claims 51 and 52 satisfy the requirements of 35 U.S.C. §112, first paragraph and, therefore, these claims are allowable and the specification is considered acceptable.

35 U.S.C. §102 & §103 REJECTIONS

The Examiner rejected claims 29, 36, 42, 45 and 46 under 35 U.S.C. §102(b) as being anticipated by Banko [USP 3,659,607]. Claims 30-35, 37, 43, 44, and 47-50 stand rejected under 35 U.S.C. §103 as being unpatentable over the cited prior art for the reasons provided on pages 7-12 of the above-referenced Office Action. More particularly, claims 30-32, 35, 37, 43, 44, 47 and 48 stand rejected under as being unpatentable over Banko [USP 3,659,607] in view of Peyman [USP 5,487,725]; claims 33-34 stand rejected under as being unpatentable over Banko in view of Peyman and further in view of Oberkamp [USP 6,485,499]; claims 47-48 stand rejected under as being unpatentable over Banko in view of Saperstein [USP 5,919,158]; claim 49 stands rejected under as being unpatentable over Banko in view of Sutherland [USP 4,258,716]; and claim 50 stands rejected under as being unpatentable over Banko and further in view of in view of Oberkamp and Peyman. Applicants respectfully traverse as discussed below.

Because claims were amended in the instant amendment, the following discussion refers to the language of the amended claims. However, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference.

Before proceeding with the discussion of the teachings and disclosures of the cited reference, Applicants first provide a general background discussion regarding the anatomy of the eye as well as conventional surgical techniques. Applicants believe that this would be of assistance in understanding the present invention as well as the beneficial advantages that flow from the use of the present invention in connection with such surgical procedures. This also would be beneficial as most of the prior art that could be of interest generally leaves out detail known to those skilled in the art, and thus leaving an incorrect picture as to what the cited art is actually describing and teaching.

As to the eye's anatomy, Applicants enclose herewith in Tab A some excerpted figures. For convenience, figure legends A-D have been added to the excerpted figures for ease of referring to them in the following discussion. Fig. A was excerpted from "Anatomica, The Complete Home Medical Reference" published by Barnes & Noble, Inc. by arrangement with Global Book Publishing Pty Ltd. (2001, reprinted 2003) and Figs. B-D were excerpted from "Wall Chart of Human Anatomy" published by Barnes & Noble by arrangement with Antographica, LLC (2001), where the 3D Anatomy provided therein was based on the National Library of Medicine's Visible Human Project.

A front view of the eye is shown in Fig. A as it would appear to one looking closely at the face of a person and Fig. B is a side view of the bony orbit with an eye therein. Figs. C and D illustrate the external musculature and vasculature of the eye.

As can be seen from a comparison of Fig. A with Figs. B-D, only a small portion of the eye is actually visible from the front, and the rest of the eye is enclosed and protected. More specifically and as can be seen from Fig. A, the cornea of the eye is visible and the rest of the eye is not visible as it is covered by a thin membrane, the conjunctiva or bulba conjunctiva that lies over and covers the front of the eye and which also forms the lining of the eyelid.

As seen from the excerpted figures as well as the text included therewith, the outer layer of the of the eye (the sclera) is covered by a thin member, the conjunctiva or the bulba conjunctiva. Thus, this thin membrane called the conjunctiva is a separate layer that is loosely connected to the globe but does not form a portion of the wall of the globe comprising the eye. As also shown in these figures, the conjunctiva or bulb conjunctiva blocks access to the exterior surface of the wall of the eye including the sclera.

Applicant would note that a common misunderstanding is that the conjunctiva forms a part of the wall of the sclera and thus is part of the structure inherently shown in various figures of issued patents which refer to the wall of the eye or the sclera. As can be seen from the foregoing, this is not just the case. In this regard, Applicants would note that in certain of the art that was identified by Applicants, while the structure of the eye may appear, the depiction does not include the conjunctiva.

Another common misunderstanding or misconception arose in connection with the parent application because the issued patents or published patent applications were written from the view of what is known to those skilled in the art. Thus, steps of the surgical technique as well as physical structure are typically missing from these documents because of this. Consequently, this leads to a misconception as to what a device is designed for. Thus, the following discussion is provided to describe the conventional surgical technique which is inherently embodied in at leats the primary and secondary references cited by the Examiner Examining Division in the above-identified Office Action.

In this regard, Applicants have attached herewith in Tabs B and C respectively, a copy of Chapter 129 of the second edition of "Retina" and a copy of Chapter 127 of the third edition of "Retina." These Chapters are both entitled "Principles and techniques of vitreous surgery." The second edition predates the filing date of the subject application and the third edition post dates the filing date. The third edition is provided to show that the surgical procedure described below in regards to the second edition was not changed in the third edition, although it does included some figures as described hereinafter that show features that are discussed in the second edition.

The second edition of Retina at page 2066 thereof provides the following as to conjunctival incisions.

> Because vitrectomy for most vitrroretinal surgery requires a three-port approach, two conjunctival incisions are required. The temporal incision for the infusion cannula and primary active tools should be 60 degrees in extent and, centered at the lateral rectus, and 2mm from the limbus. Limbal incisions cause bleeding under the surgical contact lens and result in a postoperative ridge, making the fitting of a soft contact lens difficult. A superonasal incision, 2 mm from the limbus and 30 degrees in extent, is used for the endoilluminator and secondary active instruments exchanged from the superotemproal incision.

The second edition of Retina at pages 2066-2067, which follows the discussion regarding the conjunctival incisions, provides the following discussion as to sclerotomies. See also Fig. 129-7 on page 2068.

> An assortment of same diameter (20 gauge. 0.89 mm, 0.033 inch) tools have become a de facto standard and is strongly recommended. All current cannula systems are larger, leak without a plug, and prohibit passage of some essential, axially asymmetric tools.
>
> The wounds should be linear, 1.4 mm long, and parallel to the limbus. A lancet-tipped (symmetric) blade controls the size and position better than asymmetric blades for the sclerotomies. ... A 1.44 mm linear incision rounds out to the 0.89 mm round hole, which should be the size of the blade shank. ... The infusion cannula incision should be made first just below the 3 or 9 O'clock position inferotemporally with a 20-gauge lancet blade passed toward the center of the eye but just deep enough to ensure that the widest portion of the blade and first round section is past the nonpigmented cilliary epithelium. It should be made 4 mm from the posterior to the limbus in adult eyes or 3 mm if the lens has been removed in a prior operation or if a lensectomy is to be performed. The sclerotomy can then be grasped with a 0.1 mm forceps with an angulated end to fixate the eye while the infusion cannula retention suture is being passed. The sutures passes should be parallel to the limbus, short, deep and spaced to accommodate the base plane of the infusion cannula.
>
> The second sclerotomy should be made superonasally just above the 180-degree line, 3 to 4 mm from the limbus, and parallel to the limbus. The endoilluminator tool and associated subsystems should be passed through this

> opening to stabilize the eye while making a third sclerotomy superotemporally. Scleral plugs are not required or useful at this time.
>
> The third incision should be just above the 180-degree line, parallel to the limbus, 20 gauge and 3 to 4 mm from the limbus. More anterior or differently located incisions are required in cases of congenital or pathologic abnormalities of the pars planar region or in smaller eyes.

After a discussion of various treatment procedures, the second edition of Retina provides at page 2085 the following as to the suturing of sclerotomies:

> Monofilament 8-0 nylon sutures offer the best compromise between tensile strength and leakage caused by larger-needle diameters. ... A running shoelace suture with three bits for a typical 1.4 mm 20-gauge sclerotomy is fast and easy and offers tight would closure (Fig. 129-37).

After the discussion regarding suturing of sclerotomies, the second edition of Retina at page 2085 provides the following as to the closure of the conjunctiva.

> Running 6-0 plain gut sutures for the 2 mm limbus based flap closure eliminate postoperative conjunctival foreshortening and redundancy. Suturing of Tenon's to the muscle insertion causes ptosis, limitation of ocular motility, and inadvertent conjunctival incisions during re-operation(Fig. 129-38).

In sum, the second edition of Retina describes a process where various incisions are first made in the conjunctiva for the infusion cannula and primary active tools and for the endoilluminator and secondary active instruments and then incisions are made in the sclera so that the infusion cannula, primary active tools, the endoilluminator and secondary active instruments can be inserted through the sclera into the vitreous. Also, Retina describes suturing of the incisions during the procedure and upon completion of the procedure, suturing of all the incisions in the sclera first and then closing the conjunctival opening or incisions by suturing.

To make such incisions in the sclera and to suture the scleral incisions, the conjunctiva is opened up to allow the surgeon to access to the sclera. One also can see from Figs. 129-34, 129-37 and 129-38 that the conjunctiva is pulled back to expose the sclera to give the surgeon the access required to perform a given technique. It also should be recognized that the third edition of Retina includes Fig. 127-10 which shows conjunctival limbus flaps.

It should be noted that Chapter 127 in the third edition of Retina includes Figure 127-45 that includes algorithms for common vitreoretinal disease states. This figure extends over a number of pages, but an algorithm on page 2138 is of particular note; the algorithm entitled "Close Non-Infusion Cannula Sclerotomies (*i.e.*, incisions in the sclera). The illustrated algorithm shows that the conjunctiva is to be closed after all of the sclerotomies are closed (*i.e.*, sutured closed). This is consistent with the discussion in the second edition which also described closing the infusion cannula sclerotomy last and then closing the conjunctiva.

restart

In claim 29, Applicants claim a device kit that includes at least one entry alignment device. Such an entry alignment device is configured for insertion into an eye and so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and to maintain the entry aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure. Also, the alignment device is sized such that when the entry alignment device is removed from the eye, the entry aperture formed in the sclera is sealed without the use of sutures.

In claim 42, Applicants claim a device kit including an insertion tool including a penetrating member and at least one entry alignment device. The entry alignment device is configured so as to be removably mounted to the insertion tool penetrating member and so a portion of the at least one entry alignment devices provides an entry aperture in each of the conjunctiva and sclera of the eye and to maintain the entry aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure. Also, the entry alignment device is sized such that when the entry alignment device is removed from the eye, the entry aperture formed in the sclera is one of self-sealing or sealed without the use of sutures.

As discussed in more detail below, Banko does not disclose the device kits of either claim 29 or claim 42. As also discussed below the combination of Banko any of the other cited art does not teach or suggest the device kits of claims 29 or 42.

As to Banko; comparing Figs. A-D to figures 1-5 in Banko reveals that the eye shown in which the device is to be inserted does not show the presence of the conjunctiva extending over the sclera or closing off access to the eye such as that shown in Fig. A. This is not be surprising as the description of wall of the eye in col. 3, lines 43-57 of Banko does not indicate that the conjunctiva is part of the structure being shown.

As to Banko, the technique described therein in connection with the described device, in particular the cutting blade or instrument make clear that a necessary element of the methodology, and thus a design feature necessarily embodied by the device disclosed in Banko is that the conjunctiva is first pulled back to expose the sclera before the device is inserted through the wall of the eye.

Banko describes that once the supporting means 50 is inserted into and through the wall of the eye (which is not inclusive of the conjunctiva), two mattress sutures 52 may be conveniently tightened so as to prevent any of the vitreous material within the eye from flowing out. It also is provided that such tightening of the mattress sutures establishes sealing engagement between the supporting means 50 and the wall 25 of the eye. See Banko , col. 6, lines 23-30. Banko (see col. 6, lines 49-55) further describes that when removing the supporting means, an additional pair of mattress sutures are to be gradually tightened as the supporting means is gradually removed from the wall to close-up the opening 27 in the wall 25 of the eye.

Thus, the sclerotomy formed by the device in Banko is not self-sealing as sutures are being used to seal the opening or sclerotomy. This is not surprising as the blade or piercing end shown in Figures 6-7 and described in Banko is arranged so as to form an opening, that any one skilled in the art would know, would not be self-sealing.

As indicated in the discussion above regarding Retina, and is known to those skilled in the art, a sclerotomy is an incision that is made in the sclera/ wall of the posterior segment of the eye, more preferably in the pars plana. As also indicated in the discussion in Retina, an incision is first made in the conjunctiva to expose the area of the sclera where such an incision(s) is to be made and the opening in the conjunctiva is closed by suturing after the suturing the incision in the sclera to close such a scleral incision .

Thus, the technique described for the device in Banko must inherently include making an incision in the conjunctiva to expose the sclera prior to making an incision in the sclera/wall of the eye and closing the opening in the conjunctiva after the incision in the sclera/wall of the eye is sutured closed.

Therefore, the described device in Banko is not an entry alignment device as that term is used in the claims or the subject application which is configured to provide an entry aperture in each of the conjunctiva and the sclera and so as to maintain such apertures aligned during a surgical procedure.

As to Peyman; comparing Figs. A-D to figures 5-6 and 10-11 in Peyman reveals that the eye shown in which the instrument is to be inserted does not show the presence of the conjunctiva extending over the sclera or closing off access to the eye such as that shown in Fig. A. This is not be surprising as the description of the eye in col. 8, lines 40-45 of Peyman does not indicate that the conjunctiva is part of the structure being shown.

Peyman also provides that a sclerotomy incision is made and that an instrument would be inserted through the incision. Peyman further provides that given the small size of the cutting instrument, the incision might be small enough to be self-sealing or require a single small suture. In any event, and as described in Retina, the technique known in the art at the time of Peyman was to make incisions in the conjunctiva and to pull back the conjunctiva so as to thereby expose the sclera so the surgeon could make an incision in the sclera and to later seal the scleral incision by suturing before closing the incisions in the conjunctiva.

Peyman also provides that a sclerotomy incision is made and that an instrument would be inserted through the incision. Peyman further provides that given the small size of the cutting instrument, the incision might be small enough to be self-sealing or require a single small suture. In any event, and as described in Retina, the technique known in the art at the time of Peyman was to make incisions in the conjunctiva and to pull back the conjunctiva so as to thereby expose the sclera so the surgeon could make an incision in the sclera and to later seal the scleral incision by suturing before closing the incisions in the conjunctiva.

Thus, the described device in Peyman is not an entry alignment device as that term is used in the claims or the subject application which is configured to provide an entry aperture in each of the conjunctiva and the sclera and so as to maintain such apertures aligned during a surgical procedure. Also, Peyman provides that the incision *might* be small enough to be self-sealing or require a single small suture. There is no indication in Peyman that the incision would be self sealing. It also is clear that there is no suggestion anywhere in Peyman that the device would be inserted through both the conjunctiva and the sclera. As the conjunctiva is a separate tissue layer, if one tried to form an aperture in each of the conjunctiva and the sclera using the device described in Peyman and then removed it to insert another instrument, the clinician would have to try and find the hole in the sclera because the apertures would not remain aligned. Such poking around could lead to unneeded trauma and damage to the eye.

It also should be noted that the teachings in Retina provide that conventional cannula systems are larger than the 20 gauge instruments. As is noted in the subject application as well as based on the teachings in Retina, such sized instruments would require making incisions in the sclera that would needed to be sutured to close the incision. Consequently when all the prior art is considered as a whole, the prior art teaches way from the use of an entry alignment device for forming an opening in each of the conjunctiva and sclera as the opening formed in the sclera as taught by the prior art would have to be closed by sutures which necessarily means that the conjunctiva would have to be cut (incisions made therein) and manipulated so as to expose the sclera to make the incisions in the sclera.

In sum, none of the cited references alone or in combination describe a device kit as set forth in either claims 26 or 42, which includes at least one entry alignment device. Such an entry alignment device (100a-100g) is configured for insertion into the eye and (a) so as to provide a through aperture in each of the conjunctiva (4) and sclera (6) of the eye (2) and (b) to maintain the through aperture formed in each of the conjunctiva(4) and the sclera (6) aligned during a surgical procedure and (c) so as to have a cross-section that is sized such that when the device is removed from the eye, the through aperture formed in the sclera is sealed without the use of the sutures.

In addition to not meeting the limitations of the claims, it should be recognized that the device described in Banko form incisions or sclerotomies in the sclera that are incapable of being self-sealing and thus require the use of sutures to seal the opening in the sclera following the removal of the described device. Thus, these devices inherently are incapable of meeting the limitation that the through aperture in the sclera is sealed without the sue of sutures. They also are incapable of teaching and thus meeting the limitations as set forth in claims 51-52 as well. As indicated above, the process described in Retina involves the use of sutures to seal the opening made in the sclera.

As to Peyman, the described procedure involves the pulling back of the conjunctiva in one or more places to expose the exterior surface of the wall of the eye so that the described device can be inserted through the sclera. While Peyman indicates that the opening formed "*might*" be small enough to be seal without sutures, there is no indication anywhere in Peyman, that one can arrive at an entry alignment device that would allow one to create through apertures in both the conjunctiva and the sclera and to maintain such through apertures aligned during the conduct of a surgical procedure. There also is no suggestion, teaching or suggestion anywhere in Peyman that such an entry alignment device would reduce surgical steps (*e.g.*, do not have to perform steps to form access openings in conjunctiva and to later sutures such conjunctival openings closed; do not have to seal surgical openings in sclera) as well as minimizing trauma to the eye and minimizing risk of post-operative complications that can arise from such suturing. All that Peyman appears to suggest is that one might not have to suture the sclera or only use a single suture to close the opening in the sclera. In sum, there is no motivation provided anywhere in Peyman that would suggest such an entry alignment device embodied in the claimed device kits of the present invention.

The entry alignment devices embodied in the device kits of the presently claimed invention, are configured so that they can form through apertures in each of the conjunctiva and sclera and to maintain such through openings aligned during a surgical procedure. Thus, the entry alignment devices advantageously reduce surgical steps that would be required in using the described devices in conventional techniques. Such entry alignment devices of the present invention also keep the through apertures aligned during the surgical procedure, thus a clinician can easily remove an instrument from one entry alignment device and insert another instrument without having to worry about the through apertures in the conjunctiva and sclera moving with respect to each other after removing the first instrument. Furthermore, and as suggested above, the entry alignment devices of the present invention are such as to minimize trauma to the eye as well as minimizing postoperative complications that could arise for example because of the suturing.

As to claims 30-37 and 43-50, these claims depend respectively from one of claims 29 and 42, which claims are considered to be allowable. As such each of claims 30-37 and 43-50 is considered to be allowable at least because of the dependency from an allowable base claim. This shall not, however, be considered an admission that claims 30-37 and 43-50 would not be separately patentable from the cited art. As to the other cited references, Applicants make the following brief observations.

Saperstein describes the known technique of inserting surgical instruments/ cannulas/ light probe through a sclerotomy (*i.e.*, sclerotomy incision) in the eye. Thus, Saperstein does not disclose, teach or suggest the transconjunctival methodology of Applicants and thus also does not describe, teach or suggest the device kits as claimed by Applicants. Moreover, there can be no teaching, suggestion or motivation offered in Saperstein to modify the methodology and devices in the primary reference, Banko, so as to yield either of the device kits by Applicants.

As to the other references (Oberkamp and Sutherland, Applicants would note that these are being cited for the purposes of allegedly teaching a specific limitation in one of the dependent claims. Thus, these other references do not disclose, teach or suggest the transconjunctival methodology of Applicants and thus also does not describe, teach or suggest the device kits as claimed by Applicants. Moreover, there can be no teaching, suggestion or motivation offered in either of the two other reference to modify the devices in the primary reference, Banko, so as to yield either of the device kits by Applicants.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

Verdegal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the claims being rejected on §102 grounds, are not anticipated by Banko.

As to the claims being rejected under §103 grounds, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the §103 related references cited, alone or in combination, include no such teaching, suggestion or motivation.

It is respectfully submitted that for the foregoing reasons, claims 29-37 and 42-50 are patentable over the cited references and thus satisfy the requirements of 35 U.S.C. §102(b) or §103. As such, these claims are allowable.

SEPCIFICATION OBJECTIONS

The Examiner objected to the specification of the subject application, including the ABSTRACT, and requested correction thereof. The following addresses the specific objections of the Examiner.

ABSTRACT

The ABSTRACT was objected to because of its length. The ABSTRACT was amended in the instant amendment to address the Examiner's objections. As such, the ABSTRACT, as amended, is considered acceptable.

OTHER

The Examiner objected to the specification for the reasons provided on page 4 of the above-referenced Office Action. The specification was amended as suggested by the Examiner.

Applicants would note that it appears that the specification amendments contained in the Preliminary Amendment dated October 9, 2003, that was filed with the subject application, may not have been entered or not fully entered into the subject application. The objection to page 30 of the subject application was one of the specification amendments included with this Preliminary Amendment. As indicated in the corrected Preliminary Amendment dated August 20, 2007, Applicants treated the Examiner's request as a Notice of non-compliant amendment and thus did not repeat the non-claim amendments in the corrected Preliminary Amendment. Applicants bring this to the Examiner's attention out of an abundance of caution so that the record can be checked to make sure that the other amendments and the like were entered into the record.

It is respectfully submitted that for the foregoing reasons, the specification including the ABSTRACT, satisfies applicable Patent laws and rules and, therefore is considered acceptable.

DRAWING OBJECTIONS

The Examiner objected to drawing figures for the reasons provided on pages 4-5 of the above-referenced Office Action. Attached herewith in Tab D is a replacement sheet including FIG(s). 17-19, 20A and 20B in which drawing FIG. 20A was amended as suggested by the Examiner. As such the as-amended drawing figure is considered acceptable.

OTHER MATTERS

In the Office Action (see pgs 3-4 thereof) Applicants were requested to submit another Information Disclosure Statement as there was a deficiency in the one submitted October 9, 2003. The Examiner did acknowledge that the art referred to thereon has been considered by the Examiner. Applicants enclose herewith in Tab E, a replacement Information Disclosure

Statement (*i.e.*, PTO Form SB/08) as requested by the Examiner. Applicants do not believe that an additional fee is required for submission of this corrected IDS, however, if a fee is required, Applicants authorize the Commissioner to charge the Deposit Account as indicated hereinafter.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
Edwards Angell Palmer & Dodge, LLP

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